SMG 1247.11

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Center for Veterinary Medicine

Office of Generic Animal Drugs

Division of Manufacturing Technologies

Effective Date: August 23, 2024

1. Division of Manufacturing Technologies (DCGGB).

A. Recommends raw material specifications to evaluate if the ingredients are adequate to ensure the identity, strength, quality, and purity of the generic new animal drugs; reviews the drug formulation for composition, characteristics, and accuracy.

B. Manages the evaluation of specifications and methods of analysis for the generic new animal drugs and its components in its dosage forms; recommends product expiration dates from stability data.

C. Manages the evaluation of the total manufacturing and control operations of generic new animal drugs as submitted in an application to determine adherence to the Good Manufacturing Practice Regulations; ascertains the current regulatory status of a drug firm prior to recommending approval of an abbreviated new animal drug application (ANADA).

D. Manages intramural and extramural research projects to gain further information on generic new animal drug manufacturing; manages the recommendation of regulatory methods and provides technical support when requested by FDA field laboratories.

E. Manages the development and implementation of regulations, guidance, and policies pertaining to manufacturing issues for generic new animal drugs intended for animal use.

F. Manages the evaluation of and recommendations concerning changes in the manufacturing chemistry and controls section of approved generic new animal drugs.

G. Develops short and long-range work plans and staffing need proposals for the Division.

2. Generic Drug Manufacturing Branch 1 (DCGGB1).

For sterile injectable, intramammary, and ophthalmic drug products:

A. Determines raw material specifications to evaluate if the ingredients are adequate to ensure the identity, strength, quality, and purity of the generic new animal drugs; reviews the drug formulation for composition, characteristics, and accuracy.

B. Evaluates specifications and methods of analysis for the generic new animal drugs and its components in its dosage forms; recommends product expiration dates from stability data.

C. Evaluates the total manufacturing and control operations of generic new animal drugs as submitted in an application to determine adherence to the Good Manufacturing Practice Regulations; ascertains the current regulatory status of a drug firm prior to recommending approval of an ANADA.

D. Recommends, and may participate in, intramural and extramural research projects to gain further information on generic new animal drug manufacturing; recommends regulatory methods and provides technical support when requested by FDA field laboratories.

E. Participates in the development and implementation of regulations, guidance, and policies pertaining to manufacturing issues for generic new animal drugs intended for animal use.

F. Evaluates and makes recommendations concerning changes in the manufacturing chemistry and controls section of approved generic new animal drugs.

3. Generic Drug Manufacturing Branch 2 (DCGGB2).

For oral dosage forms and topical suspension drug products:

A. Determines raw material specifications to evaluate if the ingredients are adequate to ensure the identity, strength, quality, and purity of the generic new animal drugs; reviews the drug formulation for composition, characteristics, and accuracy.

B. Evaluates specifications and methods of analysis for the generic new animal drugs and its components in its dosage forms; recommends product expiration dates from stability data.

C. Evaluates the total manufacturing and control operations of generic new animal drugs as submitted in an application to determine adherence to the Good Manufacturing Practice Regulations; ascertains the current regulatory status of a drug firm prior to recommending approval of an ANADA.

D. Recommends, and may participate in, intramural and extramural research projects to gain further information on generic new animal drug manufacturing; recommends regulatory methods and provides technical support when requested by FDA field laboratories.

E. Participates in the development and implementation of regulations, guidance, and policies pertaining to manufacturing issues for generic new animal drugs intended for animal use.

F. Evaluates and makes recommendations concerning changes in the manufacturing chemistry and controls section of approved generic new animal drugs.

4. Generic Drug Manufacturing Branch 3 (DCGGB3).

For Type A medicated articles, soluble powder, and topical solution drug products and biomass drug substances:

A. Determines raw material specifications to evaluate if the ingredients are adequate to ensure the identity, strength, quality, and purity of the generic new animal drugs; reviews the drug formulation for composition, characteristics, and accuracy.

B. Evaluates specifications and methods of analysis for the generic new animal drugs and its components in its dosage forms; recommends product expiration dates from stability data.

C. Evaluates the total manufacturing and control operations of generic new animal drugs as submitted in an application to determine adherence to the Good Manufacturing Practice Regulations; ascertains the current regulatory status of a drug firm prior to recommending approval of an ANADA.

D. Recommends, and may participate in, intramural and extramural research projects to gain further information on generic new animal drug manufacturing; recommends regulatory methods and provides technical support when requested by FDA field laboratories.

E. Participates in the development and implementation of regulations, guidance, and policies pertaining to manufacturing issues for generic new animal drugs intended for animal use.

F. Evaluates and makes recommendations concerning changes in the manufacturing chemistry and controls section of approved generic new animal drugs.

5. Generic Drug Substances and Facilities Assessment Branch (DCGGB4).

For drug substances and assessment of manufacturing facilities readiness for commercial manufacturing:

A. Determines raw material specifications to evaluate if the ingredients are adequate to ensure the identity, strength, quality, and purity of the generic new animal drugs and drug substances; reviews the drug formulation for composition, characteristics, and accuracy.

B. Evaluates specifications and methods of analysis for the generic new animal drugs and drug substances and its components in its dosage forms; recommends product expiration dates from stability data.

C. Evaluates the total manufacturing and control operations of generic new animal drugs and drug substances as submitted in an application to determine adherence to the Good Manufacturing Practice Regulations; ascertains the current regulatory status of a drug firm prior to recommending approval of an ANADA.

D. Recommends, and may participate in, intramural and extramural research projects to gain further information on generic new animal drug manufacturing; recommends regulatory methods and provides technical support when requested by FDA field laboratories.

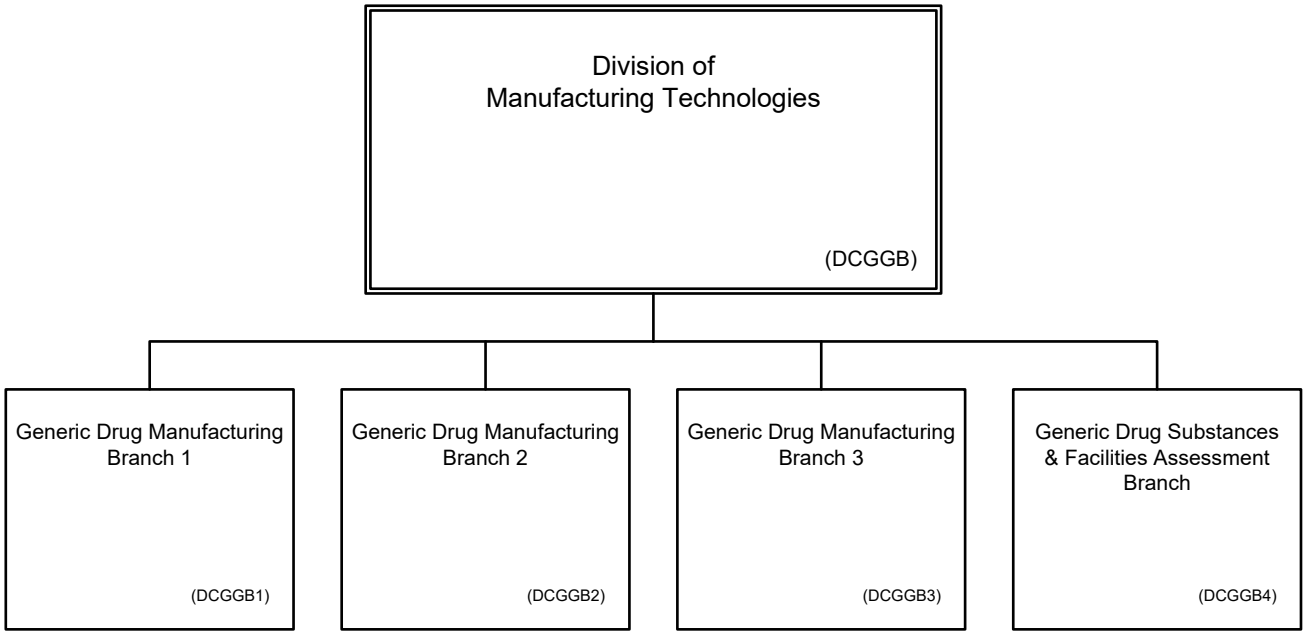
E. Participates in the development and implementation of regulations, guidance, and policies pertaining to manufacturing issues for generic new animal drugs intended for animal use.

F. Evaluates and makes recommendations concerning changes in the manufacturing chemistry and controls section of approved generic new animal drugs and drug substances.

6. Authority and Effective Date.

The functional statements for the Division of Manufacturing Technologies were approved by the Secretary of Health and Human Services on July 22, 2024, and effective on August 23, 2024.

Department of Health and Human Services
Food and Drug Administration
Center for Veterinary Medicine
Office of Generic Animal Drugs
Division of Manufacturing Technologies



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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Veterinary Medicine, Office of Generic Animal Drugs, Division of Manufacturing Technologies organization structure depicting all the organizational structures reporting to the Director:

Division of Manufacturing Technologies (DCGGB)
Generic Drug Manufacturing Branch 1 (DCGGB1)
Generic Drug Manufacturing Branch 2 (DCGGB2)
Generic Drug Manufacturing Branch 3 (DCGGB3)
Generic Drug Substances and Facilities Assessment Branch (DCGGB4)